

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IN RE SITAGLIPTIN PHOSPHATE ('708 &
'921) PATENT LITIGATION

MDL No. 19-2902-RGA

MERCK SHARP & DOHME CORP.,

Plaintiff,

v.

ZYDUS WORLDWIDE DMCC, ZYDUS
PHARMACEUTICALS (USA) INC. and
CADILA HEALTHCARE LTD.,

Defendants.

C.A. No. 21-315-RGA

SCHEDULING ORDER

This 12 day of May, 2021, the Court having waived an initial Rule 16(b) scheduling conference pursuant to Local Rules 16.1(b), and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS ORDERED that:

1. Rule 26(a)(1) Initial Disclosures. Unless otherwise agreed to by the parties, the parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) within ten days of this Order.
2. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before September 10, 2021.

3. Discovery.

a. Fact Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before March 25, 2022.

b. Document Production. Document production shall be substantially complete by September 17, 2021.

c. Requests for Admission. A maximum of **15** interrogatories, are permitted for each side. Any additional requests for admission may only be served with leave of Court. Any requests for admission directed to the authentication of documents are excluded from the limitations above.

d. Interrogatories. A maximum of **15** interrogatories, are permitted for each side. Any additional interrogatories may only be served with leave of Court.

e. Depositions.

i. Limitation on Hours for Deposition Discovery. Each side is limited to a total of 70 hours of taking testimony by deposition upon oral examination, including testimony of former employees. Any deposition lasting less than 5 hours will count as 5 hours against the total time of the side taking the deposition. These hour limits on fact depositions may be increased by Court order upon good cause shown. Separate and apart from these hour limits on fact depositions, Plaintiff may depose each witness offered as an expert by Defendant, and Defendant may depose each witness offered as an expert by Plaintiff. If a deponent testifies wholly or substantially through an interpreter, the party taking the deposition shall be permitted, on a pro rata basis, two hours of deposition time for each hour spent testifying through the interpreter. For clarity, the hour limitations described in this paragraph do not apply to depositions of third-parties or expert witnesses.

ii. Location of Depositions. The parties shall meet and confer regarding the locations of depositions, taking into account convenience for the deponent.

f. Discovery Matters and Disputes Relating to Protective Orders. Should counsel find they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall contact the Court's Case Manager to schedule an in-person conference/argument. Unless otherwise ordered, by no later than seven business days prior to the conference/argument, the party seeking relief shall file with the Court a letter, not to exceed three pages, outlining the issues in dispute and its position on those issues. By no later than five business days prior to the conference/argument, any party opposing the application for relief may file a letter, not to exceed three pages, outlining that party's reasons for its opposition. A party should include with its letter a proposed order with a detailed issue-by-issue ruling such that, should the Court agree with the party on a particular issue, the Court could sign the proposed order as to that issue, and the opposing party would be able to understand what it needs to do, and by when, to comply with the Court's order. Any proposed order shall be e-mailed, in Word format, simultaneously with filing to rga_civil@ded.uscourts.gov. If a discovery-related motion is filed without leave of the Court, it will be denied without prejudice to the moving party's right to bring the dispute to the Court through the discovery matters procedures set forth in this Order.

g. Miscellaneous Discovery Matters.

i. Contentions.

i. The parties shall make their initial disclosures under Paragraphs 3 and 4 in accordance with the Court's Default Standard for

Discovery, Including Discovery of Electronically Stored Information (“the Default Standard”).

- ii. The parties shall make their initial disclosures and Plaintiff shall make its disclosures under Paragraph 4(a) of the Default Standard within 30 days after the entry of this Order;
- iii. Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (“Zydus” or “Defendants”) shall produce its core technical documents under Paragraph 4(b) of the Default Standard within 30 days after receiving Plaintiff’s disclosure under Paragraph 4(a) of the Default Standard. At the same time Defendant produces its core technical documents, Defendant shall also produce the DMF for the sitagliptin API used in its proposed NDA products, to the extent it is in Defendant’s possession, custody, or control, or if Defendant able to obtain the DMF pursuant to a contractual right to the DMF with the DMF holder. If Defendant is not in possession, custody, or control of the DMF, and is not able to obtain the DMF pursuant to a contractual right with the DMF holder, the Defendant shall inform Plaintiff of that fact and identify the DMF holder at the same time it produces their core technical documents.
- iv. Plaintiff shall make its disclosure under Paragraph 4(c) of the Default Standard by within 30 days after receiving Defendant’s disclosure under Paragraph 4(b) of the Default Standard;

- v. Defendant shall make its disclosures under Paragraph 4(d) of the Default Standard within 30 days after receiving Plaintiffs' disclosure under Paragraph 4(c) of the Default Standard.
 - vi. The parties shall exchange supplemental infringement and invalidity contentions on February 25, 2022.
- ii. Other Pending Litigation.
- i. The parties are currently involved in litigation related to the same patent, U.S. Patent No. 7,326,708 (the "'708 patent"), concerning a different Zydus product. *See* C.A. Nos. 19-2902-RGA, 19-314-RGA.
 - ii. In an IPR related to the '708 patent, the PTAB issued a final written decision dated May 7, 2022, determining that no challenged claim was unpatentable.
- iii. Samples. At the same time that Defendant produces its core technical documents, Defendant shall disclose to Plaintiff whether it is able to produce reasonable quantities of samples (expired or unexpired as of the entry of this Order) of its (i) NDA products, (ii) API, (iii) placebo tablets of its NDA products, and (iv) the excipients used to manufacture its NDA products, each of (i)-(iv) to the extent such samples are in the Defendant's possession, custody, or control, or if Defendant can obtain such samples pursuant to a contractual right with a supplier. For clarity, if Defendant does not have such samples in its possession, custody, or control, and cannot obtain such samples pursuant to a contractual right with a supplier,

Defendant shall inform Plaintiff of those facts at the same time it produces its core technical documents.

4. Protective Order. The parties agree that the protective order entered in C.A. No. 19-2902-RGA will govern this matter. All disclosures, including expert disclosures, made by the parties in C.A. No. 19-2902-RGA will be deemed to have also been made in this matter.

5. Papers Filed Under Seal. When filing papers under seal, counsel shall deliver to the Clerk an original and one copy of the papers. A redacted version of any sealed document shall be filed electronically within seven days of the filing of the sealed document.

6. Courtesy Copies. The parties shall provide to the Court two courtesy copies of all briefs and one courtesy copy of any other document filed in support of any briefs (i.e., appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal.

7. Claim Construction. The parties acknowledge that the constructions entered by the Court in Case No. 19-2902-RGA will also apply in this matter, as it is part of the same MDL. The parties preserve their arguments and objections raised during the claim construction process in Case No. 19-2902-RGA, including in their claim construction briefing, *see* D.I. 136, No. 19-2902-RGA, for all purposes including any potential appeal in this matter.

8. Disclosure of Expert Testimony.

a. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or before April 29, 2022. Plaintiff's responsive reports, including Plaintiff's expert reports regarding objective indicia of nonobviousness, and Defendant's responsive reports are due on or before June 17, 2022. Reply expert reports are due on or before July 29, 2022. No other expert reports

will be permitted without either the consent of all parties or leave of the Court. The parties shall advise of the dates and times of their experts' availability for deposition by July 29, 2022.

Depositions of experts shall be completed on or before August 19, 2022.

b. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later September 9, 2022, unless otherwise ordered by the Court.

9. Case Dispositive Motions. There being no issues triable to a jury in this case at this time, a party may only file a motion for summary judgment if that party first obtains permission from the Court to do so.

10. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

11. Pretrial Conference. On October 14, 2022, the Court will hold a Rule 16(e) final pretrial conference in Court with counsel beginning at 9:00 a.m. The parties shall file a joint proposed final pretrial order in compliance with Local Rule 16.3(c) no later than 5 p.m. on the fourth business day before the date of the final pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d) for the preparation of the proposed joint final pretrial order.

12. Motions in Limine. Motions *in limine* shall be separately filed, with each motion containing all the argument described below in one filing for each motion. Any supporting documents in connection with a motion *in limine* shall be filed in one filing separate from the motion *in limine*. Each party shall be limited to three *in limine* requests, unless otherwise

permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three pages of argument and may be opposed by a maximum of three pages of argument, and the party making the *in limine* request may add a maximum of one additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three-page submission (and, if the moving party, a single one page reply). No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

13. Trial. This matter is scheduled for a 3-day bench trial beginning at 8:30 a.m. on October 31, 2022, with the subsequent trial days beginning at 8:30 a.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

14. ADR Process. This matter is referred to a magistrate judge to explore the possibility of alternative dispute resolution.

15. Service By E-Mail. The parties consent to service by e-mail, in accordance with Rule 5(b)(2)(E) of the Federal Rules of Civil Procedure. The parties agree that service on any party by e-mail shall be made on both Delaware and Lead counsel for that party.

IT IS SO ORDERED this 12 day of May, 2021.

/s/ Richard G. Andrews

UNITED STATES DISTRICT JUDGE